

REMARKS

This amendment is in response to the Office Action mailed September 21, 2006.

Claims 10, 11, 39 - 43, 48, 124 - 130, and 135 - 180 are pending in the application.

Claims 39 - 43, 156 - 168, 174, 176, 178, and 180 are withdrawn from consideration.

Claim 48 is rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,146,915, to Montgomery.

Claims 124 - 130 are rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,388,574, to Ingebrethsen, in view of U.S. Patent No. 5,894,841, to Voges.

Claims 10, 11, 135 - 155, 169 - 173, 175, 177, and 179 are allowed.

Amendments to the Claims

Without prejudice to the Applicants' rights to present claims of equal scope in a timely filed continuing application, to expedite prosecution and issuance of the application, the Applicants have amended Claims 10, 11, 48, 124 - 126, 129, 130, 135, 138 - 140, 146, 147, 154, 169, 170, 175, 177 and 179 and cancelled Claims 145, 148 - 153, 155, and 171 - 173. The Applicants also have presented new Claims 181 - 197. The amended claims and the new claims are supported by the specification. The amendments to the claims do not introduce new matter. Applicants respectfully submit that the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to enter the amendments to the claims and allow all amended claims.

Claim Rejections Under 35 USC § 103

Claim 48 is rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,146,915, to Montgomery ("Montgomery"). Montgomery pertains to an anesthetic vaporizer for use with anesthetic agents having low boiling points (Montgomery, abstract). The Examiner cites Montgomery as teaching "a method of generating an aerosol comprising the steps of heating a physiologically active compound via heaters 32 located within a heating-vaporization zone having a restricted cross-sectional area." The Examiner asserts that the heaters may be said to be contained within a "restricted cross-sectional area" because the vaporizer housing has a "definite shape" and "applicant has not provided any additional structural limitation to further define what constitutes as a 'restricted cross-sectional area'."

Applicants respectfully disagree in view of the elements of Claim 48 and the disclosure of Montgomery. Applicants' specification fully supports the term "restricted cross-sectional area" as used in Claim 48. However, in order to advance the present application to allowance, applicants have amended Claim 48, as set forth above, to require the step of "cooling the resulting vapor by mixing the vapor with a gas, in a ratio, to form an aerosol having a desired particle size when a stable concentration of particles is reached."

Applicants submit that the amendment to Claim 48 clearly distinguishes applicants' claimed invention from the vaporizer disclosed by Montgomery. Montgomery fails to teach cooling the resulting vapor by mixing the vapor with a gas, in a ratio, to form an aerosol having a desired particle size when a stable concentration of particles is reached as required by Claim 48. An aerosol is "an assembly of liquid or solid particles suspended in a gaseous medium" (page 1, third full paragraph; *citing* Aerosol Measurement, Willeke and Baron, Wiley-Interscience, 1993). By contrast, Montgomery discloses delivery of a gas to a patient (*i.e.*, a gaseous anesthetic agent contained within a carrier gas). *See, e.g.*, Montgomery, col. 2, lines 62-65 (referring to "the concentration of gaseous anesthetic agent in the carrier gas leaving the outlet") (emphasis added). Nowhere does Montgomery disclose or suggest an aerosol, how to make an aerosol, or any assembly of liquid or solid particles, their size or stability of their concentration.

Furthermore, Montgomery does not disclose cooling the resulting vapor by mixing the vapor with a gas. To the contrary, Montgomery states that "the heater 32 is positioned within the vaporizer so that, in addition to the vaporizing chamber 12, the passageways 6, 10 26 and regulator 14 are also heated to prevent the anesthetic condensing out on the walls of the vaporizer which would otherwise be cooler than the vaporizing chamber" (Montgomery, col. 3, lines 19-25). Thus, Montgomery actually teaches away from cooling the resulting vapor.

In light of the above arguments and the amendment to Claim 48, applicants respectfully request withdrawal of the rejection of Claim 48 under 35 USC § 103(a), over Montgomery. New Claims 181-197 which depend from Claim 48 are patentable for the same reasons as Claim 48.

Claims 124 - 130 are rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,388,574, to Ingebrethsen ("Ingebrethsen"), in view of U.S. Patent No. 5,894,841, to Voges ("Voges").

The Examiner cites Ingebrethsen as teaching a method of generating aerosol comprising the steps of depositing a physiologically active compound onto a mesh screen and heating the compound by passing a current across the mesh screen to vaporize the compound. The Examiner acknowledges that Ingebrethsen is silent with regards to the step of mixing the vapor with the carrier gas, in a ratio, to form a desired particle size when a stable concentration of particles in the gas is reached. However, the Examiner asserts that Voges teaches that the droplet size of an aerosol delivered to a patient is a function of the carrier gas pressure and velocity and concludes that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Ingebrethsen to include the step of mixing the resulting vapor with a carrier gas in a ratio to form a desired particle size since Voges teaches that it is well known in the art to control the particle size since the particle size is a function of the delivered pressure and velocity of the carrier gas.” Office Action at 4.

Applicants respectfully disagree in view of the pending claims and the disclosures of Ingebrethsen and Voges. Applicants’ Claim 124, as currently amended, is directed to: “A method of generating an aerosol comprising the steps of: (a) depositing a physiologically active compound onto an electrically conductive mesh screen; and (b) heating the mesh screen by passing a current across the mesh screen to vaporize at least a portion of the physiologically active compound.” By contrast, Ingebrethsen is directed to an aerosol delivery article that “provides delivery of aerosol particles of relatively small size without the necessity of exposing the material which is aerosolized to a significant degree of heat or high temperatures. An aerosol forming material is a multi-component material comprising an active ingredient and another ingredient having a relatively low vaporization temperature, and preferably that aerosol forming material is in the form of an emulsion. The aerosol forming material is nebulized so as to provide first stage multi-component aerosol particles of fairly large size. The first stage aerosol particles then are subjected to heat so as to vaporize the other ingredient of that aerosol and cause further dispersion of that first stage aerosol. As such, a second stage aerosol composed of fine particles of active ingredient is provided. The heat used to cause the further dispersion of the first stage aerosol is less than that sufficient to cause vaporization, thermal decomposition or undesirable chemical alteration of the active ingredient.” Ingebrethsen, abstract. (emphasis added). *See also*, Ingebrethsen, col. 2, lines 36 - 52.

Thus, Ingebrethsen is not vaporizing the physiologically active compound, as required by Claim 124. Ingebrethsen is mechanically producing a first stage aerosol, for example, by nebulization (*see, e.g.*, Ingebrethsen, col. 3, lines 12 - 14). The particles of this first stage aerosol are relatively large and contain both active ingredient and another ingredient. Ingebrethsen then heats the first stage aerosol to a temperature that is “less than that sufficient to cause vaporization . . . of the active ingredient” for the purpose of selectively vaporizing the “other ingredient” (which has a “relatively low vaporization temperature”) to provide “a second stage dispersion of aerosol particles of relatively small size.” The “other ingredient” is described at col. 7, lines 30 - 33, of Ingebrethsen, as “of a nature” and “used in an amount, such that the other ingredient is essentially pharmacologically inactive relative to the active ingredient.”

Furthermore, Ingebrethsen does not teach “depositing a physiologically active compound onto an electrically conductive mesh screen” as required by Claim 124. The heating unit described in Ingebrethsen merely provides a heated region through which the “first stage” aerosol passes as it travels through the device (*see* Ingebrethsen, col. 2, line 65 - col. 3, line 9). In the preferred embodiment shown in Fig. 1, for example, the resistive heating element is provided by winding a resistance heating wire (72) around a coiled length of a tube (77) through which the aerosol passes. Ingebrethsen states that the heating unit should have “a surface area and configuration so that a significant amount of the aerosol particles does not experience contact with components of the heating unit” to avoid deposition of the particulate material (Ingebrethsen, col. 10, line 56 - col. 11, line 2). Thus, Ingebrethsen teaches against depositing a physiologically active compound onto an electrically conductive mesh screen.

In summary, Ingebrethsen does not teach or even suggest vaporizing a physiologically active compound or depositing a physiologically active compound onto an electrically conductive mesh screen, as disclosed in applicants’ specification and claimed in pending Claims 124 - 130. In fact, Ingebrethsen teaches against heating an active ingredient to a temperature sufficient to vaporize the active ingredient and teaches against depositing a physiologically active compound onto a heating unit. As such, applicants’ claimed invention is clearly distinguishable over the teachings of Ingebrethsen.

Voges does not cure the deficiencies of Ingebrethsen. Voges pertains to a dispenser comprising a reservoir of a physiologically active substance and a droplet ejection device which is controlled to issue a predetermined number of discrete droplets of the substance from ejection

orifices upon actuation (Voges, abstract). However, the passage cited by the Examiner relates to jet nebulizers that generate an aerosol by atomizing a liquid in a carrier gas stream and merely states that the droplet size of the resulting aerosol is a function of carrier gas pressure and velocity. This teaching with respect to the effect carrier gas pressure and velocity have on droplet size in jet nebulizers (where liquid is fragmented by shear force to form droplets) is not applicable to the invention claimed by applicants where a vapor is mixed with a gas, in a ratio, to form an aerosol having a desired particle size, as disclosed and claimed by applicants. Voges does not teach or suggest the series of method steps disclosed and claimed by applicants. As such, applicants' claimed invention is clearly distinguishable over the teachings of Ingebrethsen. As stated above, Ingebrethsen teaches away from applicants' claimed invention. Therefore, even if one were to combine the teachings of Voges with those of Ingebrethsen, one skilled in the art would not be led to make applicants' invention.

Whether taken alone or in combination, neither Ingebrethsen nor Voges teaches or even suggests applicants' claimed invention. In light of the above arguments, applicants respectfully request withdrawal of the rejection of Claims 124 - 130 under 35 USC § 103(a), over Ingebrethsen, in view of Voges.

Closing Remarks

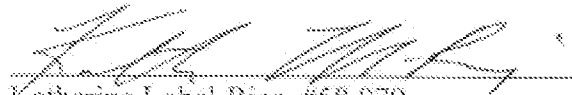
Applicants appreciate the Examiner's careful and thorough review of the application and submit that the Examiner's concerns have been addressed by the amendments and remarks above. Applicants accordingly request that the Examiner withdraw all rejections and allow the application. In the event that the Examiner believes that a telephonic discussion would expedite allowance or help to resolve outstanding issues in the prosecution of the application, the Examiner is invited to call the undersigned at the telephone number set forth below.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Applicants respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks set forth above.

Respectfully submitted,

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